K010016

OCT - 9 2001

510(k) Safety and Effectiveness Information

Submitted By: Lisa Hopkins
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, In 47402
(812) 339-2235

Device: Trade Name: Melker Cuffed Emergency Cricothyrotomy Catheter

Proposed Classification Name: Tracheostomy Tube & Tube Cuff

Predicate Devices or Legally Marketed Devices: The Pertrach — Marketed & Distributed by Pertrach, Inc. K914743

Device Description

The Melker Cuffed Emergency Cricothyrotomy Catheter consists of a connector with a flange on the proximal end connected to tubing with an inner diameter. Near the distal tip of the catheter is a cuff, or balloon. Through the catheter lumen is a dilator. The dilator provides a transition to a wire guide for insertion. The device is placed by Seldinger technique. The Melker Cuffed Emergency Cricothyrotomy Catheter will be available in 5mm i.d. and 8cm length. The catheter will be included in a set consisting of appropriately sized components.

Indications for Use

The Melker Cuffed Emergency Cricothyrotomy Catheter is used for emergency airway access when conventional endotracheal intubation cannot be performed. It is provided sterile in peel-open packages and is intended for one-time use.

Substantial Equivalence

The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to currently marketed devices. This device is similar with respect to intended use, and physical characteristics to predicate devices including The Pertrach device as listed above.

Test Data

Testing conducted on the Melker Cuffed Emergency Cricothyrotomy Catheter included:

- Cuff Pressure and Diameter Testing
- Cadaveric Percutaneous Insertion Testing
- Biocompatibility

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a cricothyrotomy catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2001

Ms. Lisa Hopkins
Regulatory Affairs Coordinator
Cook Incorporated
P.O. Box 489
Bloomington, IN 47402-0489

Re: K010016
Melker Cuffed Emergency Cricothyrotomy Catheter
Regulation Numbers: 868.5090, 868.5800
Regulatory Names: Emergency Airway Needle, Tracheostomy Tube and Tube Cuff
Regulatory Class: II (two)
Product Codes: 73 BWC, 73 JOH
Dated: August 28, 2001
Received: August 30, 2001

Dear Ms. Hopkins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Premarket Notification
Melker Cuffed Emergency Cricothyrotomy Catheter
COOK INCORPORATED

510(k) Number (if known): K010016

Device Name Melker Cuffed Emergency Cricothyrotomy Catheter

Indications for Use:

The Melker Cuffed Emergency Cricothyrotomy Catheter is used for emergency airway access when conventional endotracheal intubation cannot be performed. For emergency airway situations only. It is provided sterile in peel-open packages and intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010016